



December 20, 1029

SUBMITTED VIA EMAIL TO SAN YVETTE WILLIAMS AT WILLIAMS.SANYVETTE@EPA.GOV

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Generic Data Call In-Notice # GDCI-072500-1129

Dear SanYvette:

On September 27, 2019, ETI H2O received the Amendment to the Generic Data Call-In Notice for Products Containing Silver Particles in connection with the notice referenced above. ETI H2O submits the enclosed response in support of its registered products.

ETI H2O, a wholly owned subsidiary of PURE Bioscience, is the registrant of the following products, all of which are based on electrolytically-generated silver ions that are stabilized in citric acid as silver dihydrogen citrate (SDC):

Axenohl	72977-1	Formulation Intermediate	Approved 06/26/2001
Axen30	72977-3	Ready-to-Use, disinfectant	Approved 03/03/2003
Axen50	72977-4	Ready-to-Use, food contact sanitizer	Approved 08/06/2009
SDC3A	72977-5	Ready-to-Use, disinfectant/ food contact sanitizer	Approved 11/25/2008

These products are an MUP for making antimicrobial end use products and ready to use sprays and solutions. All of the products are aqueous solutions. Previously submitted acute toxicity studies have established a Category IV rating for the diluted products and Category III rating for the concentrated MUP.

PURE Bioscience intends to resubmit waivers for the studies as indicated in the attached Requirements Status and Registrant's Response form. These waivers are currently being reviewed and updated, and will be submitted as soon as they are available.

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771 Jamacha Road #512> El Cajon California 92019

PURE is citing previously submitted data to address the remaining Product Chemistry Data Requirements as listed below:

Guideline #	Study Title	MRID
Product Chemistry Data Requirements (Conventional Chemical)		
830.1600	Description of materials used to produce the product	MRID 471380-11
830.1620	Description of production process	MRID 471380-11
830.1650	Description of formulation process	MRID 471380-11
830.1670	Discussion of formulation impurities	MRID 471380-11
830.1700	Preliminary analysis	MRID 471380-11
830.1750	Certified limits	MRID 471380-11
830.1800	Enforcement analytical method	MRID 451610-01
830.1900	Submittal of samples	NA
830.6314	Oxidizing or reducing action	MRID 457572-01
830.6315	Flammability	MRID 457572-01
830.6317	Storage stability of product	MRID 456232-01
830.6319	Miscibility	MRID 457572-01
830.6320	Corrosion characteristics	MRID 456232-01
830.6321	Dielectric breakdown voltage	MRID 457572-01
830.7520	Particle size, fiber length and diameter distribution	MRID 50094600
830.7840	Water solubility: Column elution method, shake flask method	NA
830.6316	Explodability	MRID 457572-01

Water Solubility (830.7840) is irrelevant because all of the products are aqueous solutions. The Agency has a current CSF for each of the above referenced products on file.

The label and CSF amendments have been filed with the Agency as required in connection with the reclassification of the active ingredient from silver (PC Code 072501) to Silver ion (PC Code 072500).

Should you have any specific questions in regard to this submission, please contact me directly or our agent, Juliana Mann of Steptoe & Johnson LLP (jmann@steptoe.com; 202-429-3095).

Sincerely,
ETI H2O/ PURE Bioscience



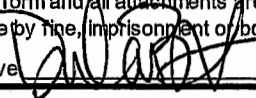
Dolana Blount
 Director of Regulatory Affairs/Microbiology

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United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174

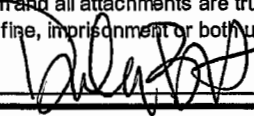
INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ETI H2O, Inc. 771 Jamacha Road #512 El Cajon CA 92019		2. Case # and Name N/A - Silver Ion (Ag1+) Chemical # and Name: 072500 Silver Ion (Ag1+)		3. Date and Type of DCI and Number 06-Jul-2012 GENERIC ID # GDCL-072500-1194	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
72977-1			YES	N/A	N/A
72977-3			YES	N/A	N/A
72977-4			YES	N/A	N/A
72977-5			YES	N/A	N/A
8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative:  VP REGULATORY					9. Date 12/20/19
10. Name of Company ETI H2O					11. Phone Number 619 596 8600

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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1. Company Name and Address ETI H2O, Inc. 771 Jamacha Road #512 El Cajon CA 92019		2. Case # and Name N/A - Silver Ion (Ag1+) Chemical # and Name: 072500 Silver Ion (Ag1+)			3. Date and Type of DCI and Number 06-Jul-2012 GENERIC ID # GDCL-072500-1194				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Applicator Exposure Data Requirements (Conventional Chemical)								
875.1400	Inhalation exposure--indoor (14, 21, 24, 26)	N				X,V,W,CC	TEP	24	9
875.1600	Application exposure monitoring data reporting (18)	N				X,V,W,CC	TEP	12	9
875.1700	Product Use Information	N				X,V,W,CC	TEP	12	1
875.2700	Product Use Information	N				X,V,W,CC	TEP	12	1
	Nontarget Plant Protection Data Requirements (Conventional Chemical)								
850.4225	Seedling emergence, Tier II (9, 11)	N				X,V,W,CC	TEP	12	9
850.4250	Vegetative vigor, Tier II (9, 11)	N				X,V,W,CC	TEP	12	9
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and II (8)	N				X,V,W,CC	TEP; TGA I	12	9
850.5400	Algal toxicity, Tiers 1 and II (8, 27)	N				X,V,W,CC	TEP; TGA I	12	9
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.							11. Date		
Signature and Title of Company's Authorized Representative  VP REGULATORY							12/20/19		
12. Name of Company ETI H2O							13. Phone Number 619 594 9600		

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			1	2	3				
	Post-Application Exposure Data Requirements (Conventional Chemical)								
875.2300	Indoor surface residue dissipation (14, 22, 25)	Y				X,V,W,CC	TEP	24	9
875.2900	Data reporting and calculations (19)	N				X,V,W,CC	TEP	12	9
875.3000	Nondietary ingestion exposure (1, 14, 23)	N				X,V,W,CC	TEP	24	9
	Product Chemistry Data Requirements (Conventional Chemical)								
830.1600	Description of materials used to produce the product	N				X,V,W,CC	EP; MP; TGA I	8	6
830.1620	Description of production process	N				X,V,W,CC	EP; MP; TGA I	8	6
830.1650	Description of formulation process	N				X,V,W,CC	EP; MP; TGA I	8	6
830.1670	Discussion of formation of impurities	N				X,V,W,CC	EP; MP; TGA I	8	6
830.1700	Preliminary analysis (12)	N				X,V,W,CC	EP; MP; TGA I	8	6

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			1	2	3				
	Product Chemistry Data Requirements (Conventional Chemical)								
830.1750	Certified limits (16)	N				X,V,W,CC	EP; MP; TGA I	8	6
830.1800	Enforcement analytical method	N				X,V,W,CC	EP; MP; TGA I	8	6
830.1900	Submittal of samples (16)	N				X,V,W,CC	EP; PAI; TGA I/MP; PAI; TGA I	8	6
830.6314	Oxidizing or reducing action (6)	N				X,V,W,CC	EP; MP; TGA I	8	6
830.6315	Flammability (3)	N				X,V,W,CC	EP; MP; TGA I	8	6
830.6317	Storage stability of product (15)	N				X,V,W,CC	EP; MP; TGA I	8	6
830.6319	Miscibility (5)	N				X,V,W,CC	EP; MP; TGA I	8	6
830.6320	Corrosion characteristics (15)	N				X,V,W,CC	EP; MP; TGA I	8	6
830.6321	Dielectric breakdown voltage (7)	N				X,V,W,CC	EP; MP	8	6

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			1	2	3				
	Product Chemistry Data Requirements (Conventional Chemical)								
830.7520	Particle size, fiber length, and diameter distribution (10, 17)	N				X,V,W,CC	TGA I or PAI	1	6
830.7840	Water solubility: Column elution method, shake flask method (16)	N				X,V,W,CC	MP; TGA I	8	6
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.1350	Mysid chronic toxicity test (20)	N				X,V,W,CC	TGA I	12	9
850.1400	Fish early-life stage toxicity test (20)	N				X,V,W,CC	TGA I	12	9
850.1735	Whole sediment: acute freshw ater invertebrates (2)	N				X,V,W,CC	TGA I	24	9
850.1740	Whole sediment: acute marine invertebrates (2)	N				X,V,W,CC	TGA I	12	9
850.1850	Aquatic food chain transfer (13)	N				X,V,W,CC	Degr; PAI; TGA I	24	9

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			1	2	3				
870.3465	Toxicology Data Requirements (Conventional Chemical) 90-day Inhalation toxicity (4, 28)	N				X,V,W,CC	TGAI	24	9
830.6316	Explosability	N				X,V,W,CC	TGAI	8	6
835.1110	Activated sludge sorption isotherm	N				X,V,W,CC	TGAI	12	9
850.6800	Modified Activated Sludge Respiration Inhibition	N				X,V,W,CC	TGAI	12	9